

PENIS ERECTION-ENHANCING DEVICE AND METHODS OF USE THEREOF

FIELD OF THE INVENTION

This invention relates to a penis erection-enhancing device and methods of treatment for males who suffer from sexual dysfunction, e.g., erectile dysfunction or premature 5 ejaculation.

BACKGROUND OF THE INVENTION

With advancing age, and also in certain pathological conditions, as well as 10 psychological conditions, men may not be able to achieve an erection with sufficient rigidity for satisfactory sexual activity. Sexual dysfunction of men, erectile dysfunction in particular, is quite likely to become a serious problem in their sex life. For more than three decades, there 15 has been an accelerated pace to solve the problems of erectile dysfunction. For example, clasps, splints, vacuum pumps with constriction rings, expensive surgical implants of many designs, pharmacological injections, urethral pellets, and most recently oral therapeutics containing sildenafil (a.k.a., Viagra<sup>®</sup>), vardenafil (a.k.a., Levitra, Nuviva), or tadalafil (a.k.a., Cialis) have been developed to treat male erectile dysfunction. Side-effects, mechanical failures, injuries, serious infections, irreversible procedures, corrective surgery, and high cost, are examples of the difficulties associated with many of these approaches to restore sexual 20 activity in males with erectile dysfunction.

Various mechanical devices can be surgically implanted in the penis to overcome 25 erectile dysfunction. Some devices are permanently rigid and hinged. Other devices provide an inflatable chamber which becomes rigid when inflated with fluid. The inflating apparatus is also implanted within the body. These devices are not always successful. Also, these invasive procedures destroy normal tissue and suffer from surgical risks, e.g., infection and hemorrhage. Moreover, there is little chance of restoring normal function when such devices are removed.

Natural therapies, e.g., acupuncture, auricular therapy, ayurvedha, Unani medicine, 30 Polarity therapy, and Bio-resonance, have also been examined for their effect on sexual function. Moreover, a full range of herbal extracts, described as male tonics, have been studied as potential therapeutics for sexual dysfunction, e.g., Yohimbine, Muia Puima, Maca, Velvet antler, Ashwagandha, *Tribulus terrestris*, Horny Goat weed. Many of these approaches suffer from various physical side-effects, or have had limited success in treating male erectile 35 dysfunction.

Viagra<sup>®</sup> promotes erectile function by blocking the action of phosphodiesterase which retards the dissolution of cyclic GMP in the penis tissue. The Viagra<sup>®</sup> drug produces side-effects, however, in certain individuals suffering from heart disease or high blood pressure. The use of Viagra<sup>®</sup> may be contraindicated in subjects with neurological disorders or peripheral

circulation deficiencies from diabetes mellitus, a narrowing of vessels in the lower limbs due to arteriosclerosis, other organic diseases, or those who have developed heart diseases. Furthermore, the drug should not be taken together with a hypotensor or an anti-angina drug. In addition, the drug is very expensive.

5 There is a continuing need in the art to provide a temporary, non-invasive device to enhance the sexual function of males, e.g., erectile dysfunction and premature ejaculation, in need thereof.

#### SUMMARY OF THE INVENTION

10 The present invention provides a safe, non-invasive device most suitable for males who suffer from sexual dysfunction (e.g., but not limited to, erectile dysfunction, premature ejaculation, and orgasmic problems). The device can also be used by males without erectile dysfunction, who wish to enhance their sexual function.

In one aspect, the invention provides a device for implementing and maintaining an erection of the penis comprising: at least one energy source wherein the energy source is selected from the group consisting of: a magnet; bipolar magnet; bimetallic plate; bioceramic bead and a battery; and wherein the device is placed in proximity to the skin of a subject in need of enhanced sexual function. In one embodiment, the at least one energy source of the device of the invention is at least one discrete region of the device. In one embodiment, at least one discrete region of the device has a width/diameter of at least about 0.1 centimeter to about 1.0 centimeter and a height of at least about 0.1 centimeter to about 1.0 centimeter. In one embodiment, at least one discrete region of the device has a width/diameter of at least about 0.1 centimeter to about 0.5 centimeter and a height of at least about 0.1 centimeter to about 0.5 centimeter. In one embodiment, at least one discrete region of the device has a width/a diameter of at least about 0.1 centimeter and a height of at least about 0.1 centimeter. In one embodiment, at least one discrete region of the device has a width/a diameter of about 0.5 centimeter diameter and about 0.3 centimeter height. In one embodiment, at least one energy source of the device is a magnet with a magnetic flux density of at least about 500-15,000 gauss. In one embodiment, the at least one energy source of the device is a magnet with a magnetic flux density of at least about 5,000-15,000 gauss. In one embodiment, the at least one energy source of the device is a magnet with a magnetic flux density of at least about 5,000-9,000 gauss. In one embodiment, the at least one energy source of the device is a magnet with a magnetic flux density of at least about 9,000 gauss. In one embodiment, the at least one energy source of the device is a magnet containing germanium. In one embodiment, the device is shaped as a cuff having inside and outside surface and inner and outer ends to receive a flaccid penis. In one embodiment, the cuff has a gap to allow expansion of the cuff. In one embodiment, the cuff further comprises an adjustable, self-closing clip. In one embodiment, the cuff has a length extending toward the penile glans a distance of at least

about 1 millimeter to about 50 millimeters. In one embodiment, the cuff has a length extending toward the penile glans a distance of at least about 1 millimeter to about 25 millimeters. In one embodiment, the cuff has a has a length extending toward the penile glans a distance of at least about 1 millimeter to about 10 millimeters. In one embodiment, the device further

5 comprises at least one temperature-sensing element. In one embodiment, the temperature-sensing element is a crystal.

In another aspect, the invention provides a method of treating a subject in need of enhanced sexual function, wherein at least one region of the penis of a subject is exposed to the device of the invention for up to 5 hours prior to sexual activity. In one embodiment of the

10 method of the invention, the at least one region of the penis exposed to the device of the invention is an M-point. In one embodiment of the method of the invention, the M-point is contacted with the south pole of at least one magnet

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic drawing illustrating embodiments of cuff-shaped penis erection-enhancing devices (a.k.a., M001) of the present invention comprising one (panel A) or more (panel B) magnetic regions.

Figure 2 is a schematic drawing illustrating one embodiment of a rope-style, cuff-shaped penis erection-enhancing device of the present invention comprising a copper/steel alloy and magnetic dots (a.k.a., M003). Panel A shows a front elevation view of the device. Panel B shows a rear elevation view of the device. Panel C shows a R.H.S. elevation view of the device. Panel D shows a plan view of the device. Panel E shows an L.H.S. elevation view of the device. Panel F shows a cross-section view of the device.

Figure 3 is a schematic drawing illustrating one embodiment of a cuff-shaped penis erection-enhancing device of the present invention. Panel A shows a front elevation view of the device. Panel B shows a rear elevation view of the device. Panel C shows a plan view of the device. Panel D shows an R.H.S. view of the device. Panel E shows an L.H.S. elevation view of the device. Panel F shows a cross-section view of the device.

Figure 4 is a schematic drawing illustrating one embodiment of a cuff-shaped penis erection-enhancing device of the present invention (a.k.a., M002). Panel A shows a front elevation view of the device. Panel B shows a rear elevation view of the device. Panel C shows an R.H.S. elevation view of the device. Panel D shows a plan view of the device. Panel E shows an L.H.S. elevation view of the device. Panel F shows a cross-section view of the device.

Figure 5 is a schematic drawing illustrating one embodiment of a cuff-shaped penis erection-enhancing device of the present invention (a.k.a., M002). Panel A shows a front view of the device. Panel B shows a plain view of the device. Panel C shows a rear view of the

device. Panel D show a right isometric view of the device. Panel E shows an enlarged isometric view of the device. Panel F shows a left isometric view of the device. Panel G shows a right view of the device. Panel H shows a left view of the device.

Figure 6 is a schematic drawing illustrating one embodiment of a cuff-shaped penis

5 erection-enhancing device of the present invention comprising titanium metal and magnetic poles or bioceramic beads or biometallic plates (a.k.a., M004). Panel A shows a front elevation view of the device. Panel B shows a rearelevation view of the device. Panel C shows an R.H.S. elevation view of the device. Panel D show a plan view of the device. Panel E shows an L.H.S. elevation view of the device. Panel F shows a cross-section view of the device.

10 Figure 7 is a schematic drawing illustrating one embodiment of a cuff-shaped penis erection-enhancing device of the present invention comprising titanium metal and magnetic poles or bioceramic beads or biometallic plates (a.k.a., M004). Panel A shows a front view of the device. Panel B shows a plan view of the device. Panel C shows a rear view of the device. Panel D shows a right isometric view of the device. Panel E shows an enlarged isometric view 15 of the device. Panel F shows a left isometric view of the device. Panel G shows a right view of the device. Panel H shows a left view of the device comprising titanium metal and magnetic poles or bioceramic beads or biometallic plates.

Figure 8 is a schematic drawing illustrating one embodiment of a cuff-shaped penis 20 erection-enhancing device of the present invention comprising titanium metal and magnetic poles or bioceramic beads or biometallic plates (a.k.a., M005). Panel A shows a front elevation view of the device. Panel B shows a rear elevation view of the device. Panel C shows an R.H.S. elevation view of the device. Panel D shows a plan view of the device. Panel E shows an L.H.S. elevation view of the device. Panel F shows a cross-section view of the device.

25 Figure 9 is a schematic drawing illustrating one embodiment of a cuff-shaped penis erection-enhancing device of the present invention comprising titanium metal and magnetic poles or bioceramic beads or biometallic plates (a.k.a., M005). Panel A shows a front view of the device. Panel B shows a plan view of the device. Panel C shows a rear view of the device. Panel D shows a right isometric view of the device. Panel E shows an enlarged isometric view 30 of the device. Panel F shows a left isometric view of the device. Panel G shows a right view of the device. Panel H shows a left view of the device.

Figure 10 is a schematic drawing illustrating the different ways a magnet can be magnetized.

## DETAILED DESCRIPTION OF THE INVENTION

### I. GENERAL

The present invention provides a safe, non-invasive device most suitable for males who suffer from sexual dysfunction (e.g., but not limited to, erectile dysfunction, premature

5 ejaculation, and orgasmic problems). The device can also be used by males without erectile dysfunction, who wish to enhance their sexual function.

The penis erection-enhancing device of the present invention can be used repeatedly over an indefinite period of time. The device readily fits a user regardless of the size of the penis. The device is safe and harmless, and can be used without the need for previous 10 medical examination and without fear of side-effects. The device needs only be worn for a few minutes to a few hours a week and it does not have to be worn during the sexual activity. Accordingly, the device is not disturbing or intrusive to the user or his sex partner.

In one embodiment, the device of the invention comprises a at least one energy source. In a preferred embodiment, the device of the invention comprises a material with magnetic 15 properties. In one embodiment, the device comprises one discrete region with magnetic properties. In another embodiment, the device comprises two regions or more regions with a magnetic composition. In yet another embodiment, the entire device is composed of a magnetic composition. The device is placed so that the southern pole of the magnet(s) is facing the skin of the subject.

20 The device of the present invention can be directly contacted with the skin of the subject or, alternatively, the device can be placed in proximity to the skin of a subject. The device is placed near, or contacted with one or more M-points. One M-point is located at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac, e.g., if one is positioned to the side of the subject, the M-point is located on the subject at the 25 highest point of the scrotal sac, in the direction of the anus. Other M-points are located in the proximal region of the penis near the pubic bone. Accordingly, in one embodiment, the device is placed near, or contacted with, one or more M-points in the region of the proximal portion of the penis near the pubic bone. In another embodiment, the device is placed near, or contacted with the M-point that lies at the posterior part of the scrotal sac, at the junction between the 30 perineum and the start of the scrotal sac. In yet another embodiment, a first device is placed near, or contacted with, one or more M-points in the region of the proximal portion of the penis near the pubic bone and a second device is placed near, or contacted with, the M-point that lies at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac.

## II. THE PENIS ERECTION-ENHANCING DEVICE

In another embodiment, the device of the invention comprises a material that serves as an energy source that is placed in proximity to the skin of a subject in need of enhanced sexual function.

5        In one embodiment, the device comprises one discrete region which is an energy source. In another embodiment, the device comprises two or more regions which are energy sources. In one embodiment, the at least one discrete region comprising an energy source has a width/diameter of at least about 0.1 cm to about 1.0 cm and a height of at least about 0.1 cm to about 1.0 cm. In one embodiment, the at least one discrete region comprising an energy source has a width/diameter of at least at least about 0.1 cm to about 0.5 cm and a height of at least about 0.1 cm to about 0.5 cm. In one embodiment, the at least one discrete region comprising an energy source has a width diameter of at least about 0.1 cm and a height of at least about 0.1 cm. In one embodiment, the at least one discrete region comprising an energy source has a width diameter of at least about 0.5 cm and a height of at least about 0.3 cm.

10      In one embodiment of the invention, the energy source of the device is a non-penetrating energy source(s). Energy sources useful in the methods of the present invention include, e.g., but not limited to, magnets; bipolar magnets; a microcurrent using a bimetallic plate or beads of two or more metals with an electropotential among them (e.g., a zinc-copper bimetallic strip which will set forth a small current on the skin using the sweat as electrolyte as a stimulus); the source of electrical stimulation can be from an external source (e.g., a tiny battery incorporated in the device of the invention or attached to an external source); bioceramic beads (positioned on the inner side of the device of the invention and in contact with the skin of the subject) that emit infrared rays (e.g., far infrared rays) to the skin surface; crystals that balance the bodies harmonic wavelengths (see, e.g., Figure 6 through Figure 9). The bioceramic beads useful in the methods of the invention may be composed of one or more metal oxides.

15      In one embodiment of the invention, the energy source of the device is one or more bioceramic beads (positioned on the inner side of the device of the invention and in contact with the skin of the subject) which are activated by the body temperature of a subject to emit energy (e.g., far infrared rays) that can penetrate tissue of the subject. In one embodiment of the invention, the bioceramic beads contain at least one metal oxide.

20      The energy source(s) of the device may be any shape or dimension. In one embodiment, the energy source(s) of the device is dot-shaped. Further, the energy source(s) of the device may be comprised of a plurality of subregions with the same or differing shape, dimension. In one embodiment, the device of the invention comprises a material with magnetic properties that is placed in proximity to the skin of a subject in need of enhanced sexual function such that the southern pole of the magnet(s) is facing the skin of the subject.

25      In one embodiment of the invention, the energy source of the device is one or more bioceramic beads (positioned on the inner side of the device of the invention and in contact with the skin of the subject) which are activated by the body temperature of a subject to emit energy (e.g., far infrared rays) that can penetrate tissue of the subject. In one embodiment of the invention, the bioceramic beads contain at least one metal oxide.

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35      In one embodiment of the invention, the energy source of the device is one or more bioceramic beads (positioned on the inner side of the device of the invention and in contact with the skin of the subject) which are activated by the body temperature of a subject to emit energy (e.g., far infrared rays) that can penetrate tissue of the subject. In one embodiment of the invention, the bioceramic beads contain at least one metal oxide.

In one embodiment, the device comprises one discrete region with magnetic properties (see, e.g., Figure 1 through Figure 9). In another embodiment, the device comprises two or more regions with a magnetic composition (see, e.g., Figure 1 through Figure 9). In yet another embodiment, the entire device is composed of a magnetic composition.

5        In one embodiment, the device comprises at least one magnetic region with a potential magnetic flux density of at least about 500-15,000 gauss. In another embodiment, the device comprises at least one magnetic region with a potential magnetic flux density of at least about 5,000-15,000 gauss. In yet another embodiment, the device comprises at least one magnetic region with a potential magnetic flux density of at least about 5,000-9,000 gauss. In still  
10      another embodiment, the device comprises as least one magnetic region with a potential magnetic flux density of at least about 9,000 gauss.

The device can be directly contacted with the skin of the subject or, alternatively, the device can be placed in proximity to the skin of a subject. The inventor identified areas on the skin, termed "M-points," with a role in erectile function by measuring the electrical resistance of  
15      points on the penis surface and scrotal area and charting an electrical map of the penis and scrotal area so as to identify the control points of the male organ tonus. For example, one M-point is located at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac. Other M-points are located in the proximal region of the penis near the pubic bone. Specifically, M-points in this region include, but are not limited to,  
20      positions on the dorsal aspect (12 o'clock position), the ventral aspect (6 o'clock position), as well as both sides (3 o'clock position and 9 o'clock position, respectively) of the proximal region of the penis near the pubic bone. Accordingly, in one embodiment, the device of the present invention is placed near, or contacted with, the region of the proximal portion of the penis near the pubic bone. In another embodiment, the device of the present invention is placed near, or  
25      contacted with one or more M-points in the region of the proximal portion of the penis near the pubic bone where the surface electrical resistance is lower than the surface electrical resistance in neighboring regions of the penis. In yet another embodiment, the device of the present invention is placed near, or contacted with, the M-point that lies at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac where  
30      surface electrical resistance is lower than the surface electrical resistance in neighboring areas of this region.

The device of the present invention can be any suitable shape, e.g., disc, square, triangle, rectangle, circle, oval, trapezoid, rod, or cuff. The device can be comprised of any suitable material, or combination of materials, e.g., but not limited to, metal (e.g., titanium, copper, steel, gold, silver), ceramic, glass, plastic, rubber, latex, and textile, (e.g., silk and

wool). The device can be rigid, flexible or elastic. The device can have a smooth surface or a textured surface, e.g. twisted rope-style.

In one embodiment, the device of the invention contains at least one temperature sensing element. A temperature-sensing element useful in the device of the invention is a 5 temperature-sensitive crystal. Contacting the temperature sensing element of the device with a subject can indicate a change in temperature of the temperature sensing element relative to the temperature prior to contacting the temperature sensing element of the device with the subject. An alteration in the temperature of the temperature-sensing device can indicate a change in the local blood flow or metabolism of the subject. A subject may monitor changes in temperature of 10 the temperature-sensing elements of the device.

As detailed in Figure 10, magnets can be magnetized such that they have different directions of magnetization. In some embodiments of the invention, the device of the present invention comprises magnetic materials that are conventional magnets with one pole on each side of the magnet, i.e., North pole on one side, South pole on the other side of the magnet. In 15 one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are oriented through the thickness of the magnet. In one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are axially oriented. In one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are axially oriented in segments. In one embodiment, the device 20 of the present invention has magnetic materials wherein the magnetic field(s) are oriented laterally, multipole on the face. In one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are multipole, oriented in segments on the outside diameter. In one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are multipole, oriented in segments on one face. In one 25 embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are radially oriented. In one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are oriented through the diameter. In one embodiment, the device of the present invention has magnetic materials wherein the magnetic field(s) are oriented in segments on the inside diameter. In one embodiment, the device of the 30 invention has magnetic materials wherein the magnetic fields are diametrical oriented. In one embodiment, the device of the present invention has more than one magnetic materials and the orientation of magnetic field(s) of at least one of the materials is different from the orientation of one or more of the magnetic field(s) of the other magnetic materials.

The magnetic region(s) of the device may be comprised of permanent or temporary 35 magnets. Permanent magnets suitable for use in the present invention, include, but are not limited to, e.g., ceramic, alnico, samarium cobalt, neodymium iron boron, injection-molded and

flexible. In one embodiment of the invention, the magnet(s) of the device of the invention contain germanium metal in one of the poles. Inclusion of germanium into the magnet(s) of the device of the present invention may increase the oxygen carrying capacity of the blood to the cells of the subject.

5 Ceramic, also known as Ferrite, magnets are made of a composite of iron oxide and barium/strontium carbonate. These materials are readily available and at a lower cost than other types of materials used in permanent magnets making it desirable due to the lower cost. These magnets are also made in different grades. The anisotropic method delivers the highest energy product among ceramic magnets at values up to 3.5 MGOe (Mega Gauss Oersted).

10 Ceramic magnets have a good balance of magnetic strength, resistance to demagnetizing and economy.

Alnico magnets are made up of a composite of aluminum, nickel and cobalt with small amounts of other elements added to enhance the properties of the magnet. Alnico magnets have good temperature stability, good resistance to demagnetization due to shock but they are 15 easily demagnetized. Sintering offers superior mechanical characteristics, whereas casting delivers higher energy products (up to 5.5 MGOe) and allows for the design of intricate shapes. Two very common grades of Alnico magnets are 5 and 8. These are anisotropic grades and provide for a preferred direction of magnetic orientation. Alnico magnets have been replaced in many applications by ceramic and rare earth magnets.

20 Samarium cobalt is a type of rare earth magnet materials that are highly resistant to oxidation, have a higher magnetic strength and temperature resistance than Alnico or Ceramic materials. Introduced to the market in the 1970's, samarium cobalt magnets continue to be used today.

Neodymium Iron Boron (NdFeB) material is another type of rare earth magnetic 25 materials. This material has similar properties as the Samarium Cobalt except that it is more easily oxidized and generally doesn't have the same temperature resistance. NdFeB magnets also have the highest energy products approaching 50MGOe. Their high energy products lend themselves to compact designs that result in innovative applications and lower manufacturing costs. NdFeB magnets are highly corrosive. Surface treatments have been developed that 30 allow them to be used in most applications. These treatments include gold, nickel, zinc and tin plating and epoxy resin coating.

Injection-moldable magnets are a composite of resin and magnetic powders of different materials allowing parts to be made in an injection molding process. Energy products are dependent upon the magnetic powders used in fabrication. The molding process allows for the 35 manufacture of more complex shapes. These magnets are usually lower in magnetic strength as there are limitations to the degree of loading.

Flexible magnets are very similar to the injection molded magnets but are produced in flat strips and sheets. These magnets are lower in magnetic strength and very flexible depending on the materials that were used in the compound with the magnetic powders. Vinyl is often used in this type of magnet as the binder.

5 The device may be held in the area of one or more M-points by any suitable means. Likewise, the device can be temporarily affixed to one or more M-points by any suitable means, e.g., bandage, elastic band, or adhesive. The device can be removed for later reuse. The device may be removed prior to sexual activity or the device may be worn during sexual activity.

10 The magnetic region(s) of the device may be any shape or dimension suitable to yield the desired magnetic flux density. In one embodiment, the magnetic region(s) of the device is dot-shaped. Further, the magnetic region(s) of the device may be comprised of a plurality of subregions with the same or differing shape, dimension, or magnetic strength, *i.e.*, magnetic flux density potential, dimension, suitable to yield the desired magnetic flux density. In one 15 embodiment, the magnetic region(s) of the device has a diameter of at least about 0.1-1.0 cm and a height of at least about 0.1-1.0 cm. In one embodiment, the magnetic region(s) of the device has a diameter of at least about 0.1-0.5 cm and a height of at least about 0.1-0.5 cm. In yet another embodiment, the magnetic region(s) of the device has a diameter of at least about 0.1 cm and a height of at least about 0.1 cm. In yet another embodiment, the device of the 20 invention comprises a dot-shaped magnetic region of about 0.5 cm diameter and about 0.3 cm height.

In one embodiment, the device comprises a material with magnetic properties in the shape of a cuff which encircles the shaft of the penis at its proximal portion near the pubic bone. In an alternate embodiment, the cuff has a gap which allows for appropriate adjustment 25 of the device to the girth of the penis as well as to accommodate expansion of the device and to prevent penis tissue injury (see Figure 1). In another embodiment, the device is fitted with an adjustable self-closing clip. This clip can be tightened or loosened by the wearer such that such that blood flow from the penis is restricted. This can serve to assist in sustaining or prolonging an erection of the penis. This is particularly useful when the subject wears the 30 device of the invention during sexual intercourse or foreplay.

In one embodiment, the cuff has one (see, e.g., Figure 1, panel A) discrete magnetic region. In another embodiment, the cuff has two or more discrete magnetic regions (see, e.g., Figure 1, panel B). The discrete magnetic regions may have the same or differing magnetic flux density potential. The regions may be placed in a variety of orientations so long as the 35 southern pole of one magnetic region is oriented toward the skin in the area of the proximal portion of the penis near the pubic bone, e.g., region with one or more M-points. In one

embodiment of the invention the cuff has a length, extending distally toward the penile glans a distance of at least about 1 mm to about 50 mm. In one embodiment of the invention the cuff has a length, extending distally toward the penile glans a distance of at least about at least about 1 mm to about 25 mm. In one embodiment of the invention the cuff has a length,

5 extending distally toward the penile glans a distance of at least about at least about 1 mm to about 10 mm.

### III. TREATING MALE ERECTILE DYSFUNCTION USING THE PENIS ERECTION-ENHANCING DEVICE

In one embodiment, the present invention provides a method of treating a subject in need of enhanced sexual function the method comprising exposing one M-point, or more than one M-point, e.g., two, three, four, or more M-points, of a mammalian subject in need of treatment to the southern pole of one or more magnetic regions of the device of the present invention for up to 5 hours prior to sexual activity, e.g., sexual intercourse. Exposure of one M-point, or more than one M-point, e.g., two, three, four, or more M-points, to the southern pole of 15 one or more magnetic regions of the device of the present invention may be performed once daily or more than once each day, or a few times a week, for a period of days, or for a period of weeks, or for a period of months until the subject experiences improved erectile function relative to the erectile function of the subject prior to use of the device of the present invention.

In another embodiment, the present invention provides a method of treating a subject in need of enhanced sexual function the method comprising exposing one M-point, or more than one M-point, e.g., two, three, four, or more M-points, of a mammalian subject in need of treatment to one or more bipolar magnets of the device of the present invention for up to 5 hours prior to sexual activity, e.g., sexual intercourse. Exposure of one M-point, or more than one M-point, e.g., two, three, four, or more M-points, to the bipolar magnet(s) of the device of 25 the present invention may be performed once daily or more than once each day, or a few times a week, for a period of days, or for a period of weeks, or for a period of months until the subject experiences improved erectile function relative to the erectile function of the subject prior to use of the device of the present invention.

In another embodiment, the present invention provides a method of treating a subject in need of enhanced sexual function the method comprising exposing one or more regions of the penis of a mammalian subject in need of treatment to an energy source(s) on the device of the present invention for up to 5 hours prior to sexual activity, e.g., sexual intercourse. The regions of the penis exposed to the energy source(s) may be one M-point, or more than one M-point, e.g., two, three, four, or more M-points. The exposure of the penis may be to the device of the 35 present invention may be performed once daily or more than once each day, or a few times a week, for a period of days, or for a period of weeks, or for a period of months until the subject experiences improved erectile function relative to the erectile function of the subject prior to use

of the device of the present invention. In one embodiment, the energy source is a non-penetrating energy source.

The subject may be any mammal, e.g., bull, horse, rabbit, pig, dog, or cat, in need of enhanced sexual function. In a preferred embodiment the mammalian subject is a human

5 subject.

Generally, the device is used for as long as it is comfortable to the subject. When the subject feels tingling or "a sensation of fullness" in the zone of application, the device can be removed. In a preferred embodiment, the device is applied for about 3 hours or less.

Ordinarily, the user need not be sexually aroused by massage, foreplay, or by use of a 10 vacuum chamber before applying the device for successful operation. The user of the device of the invention can experience enhanced sexual function as manifested by effects and advantages such as, e.g., improved early morning erection, increased erectile frequency, increased penile strength, decreased post-ejaculatory recovery time, increased intercourse frequency, increased scrotal tone, *i.e.*, tension in the scrotal tissue that brings the testicles 15 closer to the body, or increased penile length and girth.

Though typical preferred embodiments, the effects and advantages of the present invention are not limited to them. It should be construed that the present invention may be practiced in different manners by changing the application methods within the range of the effects described later in order to fulfill the purposes mentioned above.

20 The present invention, compared with the drug Viagra® does not require prior medical consultation before use and is not contraindicated for diabetics, hypertensive subjects and patients suffering from angina. In addition, it does not have to be purchased at high cost after each time of use. It does not cause fear among users of side-effects or excessive medical effect by overdose, either. It does not burden the heart or other organs. It can be used while 25 maintaining the natural physical state of the user without causing any adverse side-effects.

The following observations have been made in human trials where the subject applied a device of the present invention as a cuff around the base of the penis for up to three hours per day.

Day 1	A little tingling or warm sensation will often be felt.
Day 2, 3	Stronger morning erections, slight increase in penile girth and temperature very often noted even at this early stage.
Day 4, 5, 6, 7	Stronger erections, more control during intercourse, and shorter recover time post ejaculation.

After 2 weeks of daily use, almost 90% of users feel fully energized in their male functions and at this point a maintenance regime can be started.

Each week, 2 sessions of 30 mins up to 3 hours can be maintained depending on physical condition of the person and his sexual activity frequency.

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## EQUIVALENTS

While the invention has been described in connection with the specific embodiments thereof, it will be understood that it is capable of further modification. Furthermore, this application is intended to cover any variations, uses, or adaptations of the invention, including such departures from the present disclosure as come within known or customary practice in the art to which the invention pertains, and as fall within the scope of the appended claims.

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